

Remarks

The invention relates to devices for conducting assays, including qualitative, semi-quantitative and quantitative determinations of a plurality of analytes in a single test format. The instant method and apparatus claims refer to devices comprising one or more capillary channels, in which the relative hydrophobicity of regions within at least one capillary channel differs. In certain embodiments, this differing hydrophobicity is used to control the rate and/or direction of fluid flow through the devices.

The Examiner states that claims 74-93 as filed in the preliminary amendment were renumbered as 1-20 respectively. However, Applicant notes that although the claims were numbered from 74-93, there was a duplicate of claim 78. Thus 21 claims were actually filed. This is consistent with the Examiner's restriction which refers to claims 1-18 as group I and claims 19-21 as group II.

Claims 6 and 19-21 have been cancelled herein. Notwithstanding the foregoing, Applicant expressly reserves the right to pursue subject matter no longer claimed in the instant application in one or more applications that may claim priority hereto.

Applicant respectfully requests reconsideration of the claimed invention in view of the foregoing amendments and the following remarks.

Non Art-Based Remarks

Restriction

Applicant affirms the provisional election of Group I (claims 1-18) in response to the restriction requirement. Applicant has cancelled non-elected claims 19-21 herein.

35 U.S.C. § 112, second paragraph

The Examiner indicates that claim 6 should be deleted, as it is allegedly a duplicate of claim 5. Claim 6 has been cancelled.

Information Disclosure Statement

Applicant is filing herewith under separate cover the missing references mentioned by the Examiner and some additional references not previously submitted.

Art-Based Remarks

Obviousness-type double patenting

Applicant acknowledges the rejection of claims 1-18 as allegedly being unpatentable over U.S. Patents 6,156,270; 6,019,994; 5,885,527; and 5,458,852. Applicant believes that the listing of U.S. Patent No. 6,019,994 is a typographical error, and that the Examiner intends U.S. Patent No. 6,019,944. Should the Examiner agree with Applicant regarding the identity of the U.S. Patents at issue, and should the claims as presently submitted be otherwise allowable, Applicant will submit a terminal disclaimer. Applicant respectfully requests clarification of the rejection.

35 U.S.C. § 102

Applicant respectfully traverses the rejection of claims 1-18 under 35 U.S.C. §102(b), as allegedly being anticipated by Kuhn *et al.*, U.S. Patent 5,202,268 (“the ‘268 patent”). For the sake of accuracy, Applicant notes that the ‘268 patent issued after the effective filing date of the present application (May 21, 1992) on an application filed before the filing date of the instant application, and so is presumably not prior art under 35 U.S.C. §102(b), but rather under 35 U.S.C. §102(e).

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). *See also*,

MPEP §2131. The Examiner bears the initial burden of establishing a *prima facie* case of anticipation. Only once that *prima facie* case has been established does the burden shift to the applicant to rebut the *prima facie* case. *See, e.g., In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

The Examiner points with particularity to the disclosure of a liquid flow path in the '268 patent through two porous layers, and to claim 4, which states that one of the layers may be hydrophilic and the other hydrophobic. Critical to the rejection is the Examiner's belief that the flow path through these porous layers is equivalent to flow through the "capillary channel" of the instant claims. Paper no. 9, page 4 ("[t]he taught flow path has been read on the claimed capillary channel."). Applicant respectfully disagrees with the view that a porous layer is equivalent to a capillary channel.

It is well established that terms in a claim must be interpreted in light of the specification, and the claims must be read as they would be interpreted by those of skill in the art. *See, MPEP §§ 2111 and 2111.01*. The Examiner's interpretation is contrary to the plain meaning of the term "channel" given to the term by those of skill in the art, and to the teachings of the instant specification.

As evidence of this fact, Applicants provide herewith a declaration of one of skill in the art, Dr. Kenneth F. Buechler, describing how the term "capillary channel" should be properly interpreted. In his declaration, Dr. Buechler begins with the common meaning of the term "channel," defined in Merriam Webster's Collegiate Dictionary as being "a usually tubular enclosed passage: CONDUIT." For the Examiner's convenience, a copy of this definition is provided herewith (APPENDIX 1). Dr. Buechler explains that the skilled artisan would understand that flow through a porous material as disclosed in the '268 patent is both tortuous and random, and that, therefore, a porous material is not equivalent to a "capillary channel." Dr. Buechler also notes that the instant specification clearly distinguishes between porous materials and capillary channels.

Thus, in view of the Buechler declaration, and the opinion that one of ordinary skill in the art would interpret the term “capillary channel” to be something different from a porous surface, it is concluded that the skilled artisan would readily acknowledge that the ‘268 patent does not anticipate the pending claims. In claim 1 of the present application, the capillary channel comprises a first capillary region comprising a hydrophilic surface, and a second capillary region comprising a hydrophobic surface adjacent to this first region. In contrast, the ‘268 patent discloses a first and second layer formed from “a composite structure of porous materials” through which fluid flows. ‘268 patent, column 1, lines 63-64. The “porous members” (column 2, line 57) making up this composite structure are entirely different from the “capillary channel” of the present claims. Indeed, the specification indicates that it is problems with devices containing porous materials that the present specification hopes to avoid. *See, e.g.*, specification, page 3. This same distinction exists for those claims dependent from claim 1, and claims 13-17.

Accordingly, the ‘268 patent does not anticipate the claims because it fails to teach each and every limitation. Thus, the Examiner is requested to reconsider and withdraw the rejection over Khun et al. (the ‘268 patent).

Applicant also notes that the Examiner has not indicated how the cited publication reads on claims 2 and 6 and their dependent claims. These claims describe the use of a hydrophobic surface to control the rate or direction of flow within a device. Likewise, the Examiner has not indicated how the cited publication reads on claims 3 and 12, which indicate that a hydrophobic region is used to delay fluid flow until rendered hydrophilic. As discussed by Dr. Buechler in paragraph 9 of his declaration, the ‘268 patent does not disclose these elements of the claims. Should the Examiner disagree, Applicant respectfully requests that the Examiner indicate where such elements may be found in the cited patent in a non-final office action, so that Applicant may have a reasonable opportunity to respond.

Because the cited ‘268 patent fails to teach each and every element of the present claims, Applicant respectfully submits that no *prima facie* case of anticipation has been established. Applicant therefore requests that the rejection under 35 U.S.C. §102 be reconsidered and

withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicant respectfully submits that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that they may be resolved without the need for an additional action.

Respectfully submitted,

By



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(winter changed to spring) 6 : to put on different clothes 7 : EX-
CHANGE, SWITCH (neither liked his seat so they changed with each other)
change *n* — change hands : to pass from the possession of one
owner to that of another (moncy changes hands many times)
CHANGE, ALTER, VARY, MODIFY mean to make or become different.
CHANGE implies making either an essential difference often amounting
to a loss of original identity or a substitution of one thing for another
(changed the shirt for a larger size). ALTER implies a difference in some
particular respect without suggesting loss of identity (slightly altered
the original design). VARY stresses a breaking away from sameness,
duplication, or exact repetition (vary your daily routine). MODIFY sug-
gests a difference that limits, restricts, or adapts to a new purpose:
(modified the building for use by the handicapped).

change *v* (13c) 1 : the act, process, or result of changing: as a : AL-
TERATION (a ~ in the weather) b : TRANSFORMATION (a ~ of vast
social ~) (going through ~s) c : SUBSTITUTION (a ~ of scenery) d
: the passage of the moon from one monthly revolution to another;
also : the passage of the moon from one phase to another 2 : a fresh
set of clothes 3 *Brit.* EXCHANGE 3a 4 : a : money in small denomina-
tions received in exchange for an equivalent sum in larger denomina-
tions b : money returned when a payment exceeds the amount due c
: coins esp. of low denominations (a pocketful of ~s) d : a negligible
additional amount (only six minutes and ~ left in the game) 5 : an
order in which a set of bells is struck in change ringing 6 : CHANGE-UP
changeable *adj* (13c) : capable of change: as a : able
or apt to vary (~ weather) b : subject to change: ALTERABLE c
: FICKLE d : IRIDESCENT — change-able-ly *adv* — change-able-*ble* *adv*
change-able-ness *n* (1591) : notably variable: UNCERTAIN —
change-able-*ly* *adv* — change-able-*ness* *n*
change-constant *adj* (1580) : marked by the absence of change
change-less *adj* (1537) 1 *archaic*: TURNOAT 2 : a child
secretly exchanged for another in infancy 3 *archaic* : IMBECILE —
change-ling *n* (1577) 1 *archaic*: TURNOAT 2 : a child
secretly exchanged for another in infancy 3 *archaic* : IMBECILE —
change-ling *adj*
change off *v* (1873) 1 : to alternate with another at doing an act 2
: to alternate between two different acts or instruments or between an
action and a rest period
change of heart (ca. 1828) : a reversal in position or attitude
change of life (1834) : CLIMACTERIC 2
change of pace (1912) 1 : CHANGE-UP 2 : an interruption of continuity
by a shift to a different activity
change-over *n* (1907) 1 : CONVERSION, TRANSITION 2
: a pause in a tennis match during which the players change sides of
the court
change ringing *n* (1872) : the art or practice of ringing a set of tuned
bells (as in the bell tower of a church) in continually varying order
change-up *n* (1949) : a slow pitch in baseball thrown with
the same motion as a fastball in order to deceive the batter
channel *n* (14c) 1 : the bed where a natural stream of water
runs b : the deeper part of a river, harbor, or strait c : a strait or
narrow sea between two close landmasses d : a means of communica-
tion or expression: as (1) : a path along which information (as data or
music) in the form of an electrical signal passes (2) *pl* : fixed or
official course of communication (went through established military
~s with his grievances) e : a way, course, or direction of thought or
action (new ~s of exploration) f : a band of frequencies of sufficient
width for a single radio or television communication g : CHANNELER
2 a : a usu. tubular enclosed passage: CONDUIT b : a passage created
in a selectively permeable membrane by a conformational change in
membrane proteins 3 : a long gutter, groove, or furrow 4 : a metal
bar of flattened U-shaped section
channel vt -neled or -nelled; -nel-ing or -nel-ling (15c) 1 a : to
form, cut, or wear a channel in b : to make a groove in (~ a chair leg)
2 : to convey or direct into or through a channel (~ his energy into
constructive activities) 3 : to serve as a channeler or intermediary for
channel *n* [alter. of chainwale, fr. 'chain + 'wale] (1769) : one of the
flat ledges of heavy plank or metal bolted edgewise to the outside of a
ship to increase the spread of the shrouds
channel bass *n* (1887) : a large coppery drum (*Sciaenops ocellatus*)
chiefly of the Atlantic coast of No. America that has a black spot at the
base of the tail and is an important game and food fish — called also
red drum, redfish
channel catfish *n* (1820) : a large black-spotted catfish (*Ictalurus punctatus*) that is an important freshwater food fish of the U.S. and
Canada — called also channel cat
chan-nel-er *n* (1987) : a person who conveys thoughts or
energy from a source believed to be outside the person's body or conscious
mind; specif: one who speaks for nonphysical beings or spirits
chan-nel-ize *v* (1987) vi -sized; -iz-ing (1609) 1 : CHANNEL 1, 2
2 : to straighten by means of a channel (~ a stream) — chan-nel-iza-
tion *n* (1987) 3 : a shan-shan
chan-sion *n* (1602) 1 : a writer or
singer of chansons: esp. a cabaret singer
chant *v* (1671) 1 : to sing in a rhythmic monotonous repetitive tone ~
2 : to celebrate or praise in song or chant
chant *n* (1671) 1 : SONG 2 a : PLAINSONG b : a rhythmic monotonous
utterance or song (the ~ of an auctioneer) c : a composition for
chanting
chanter *n* (14c) 1 : one that chants: a : CHORISTER b
: CANTOR 2 : the chief singer in a chanty 3 : the reed pipe of a bag-
pipe with finger holes on which the melody is played
chanterelle *n* (1775) : a fragrant edible
mushroom (*Cantharellus cibarius*) of rich yellow color

chan-teuse *n* (1888) 1 : a woman who is a concert or nightclub singer
chan-tee or chan-ty *n* (1888) 1 : a song sung by sailors in rhythm with
their work
chan-tic-eer *n* (14c) 1 : a rooster in
verse narratives, fr. OF *Chanteler*, rooster in the *Roman de Renart*
(14c) : ROOSTER
Chan-til-ly lace *n* (1848) : a delicate
silk, linen, or synthetic lace having a six-sided mesh ground and a floral
or scroll design — called also *Chantilly*
chan-try *n* (14c) 1 : an endowment for the chanting of masses com-
monly for the founder 2 : a chapel endowed by a chantry
Cha-nu-ka *n* (1888) 1 : a Jewish
holiday 2 : a *menorah* (a candelabrum with seven branches) 3 : a
candle used in the *menorah* 4 : a *synagogue* 5 : a *synagogue* 6 : a
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